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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Mary T. Am Ende, et al. :

APPLICATION NO.: 10/611,586 : Examiner: To Be Assigned

FILING DATE: June 30, 2003 : Group Art Unit: To Be Assigned

TITLE: SUSTAINED RELEASE FORMULATIONS

FOR GROWTH HORMONE

SECRETAGOGUES

Hon. Commissioner for Patents

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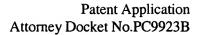
Sir:

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. § 1.97 ET SEQ.

Applicant(s) herein make(s) available to the U.S. Patent and Trademark Office a copy of PTO-FB-A820 which lists the references cited by the applicant(s), copies of which are enclosed.

The Examiner is requested to consider carefully the complete text of these references in connection with the examination of the above-identified application in accord with 37 C.F.R. § 1.104(a). It is believed the Examiner will concur with applicant's belief that the subject matter presently claimed is neither anticipated nor rendered obvious by the foregoing references.

It is requested that the references listed on the attached form PTO-FB-A820 be included in the "References Cited" portion of any patent issuing from this application (M.P.E.P. § 1302.12).





A prompt and favorable response is earnestly solicited.

Date: 30 SEPTEMBER 2003

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Respectfully submitted,

John A. Wichtowski

Attorney for Applicant(s)

Reg. No. 48,032



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| | us | 5 | 9 | 1 | 9 | 7 | 7 | 7 | 7/9/99 | Hansen, et al. | 514 | 183 | | |
| | us | 5 | 9 | 4 | 5 | 4 | 1 | 2 | 8/31/99 | Fuh, et al. | 514 | 176 | | |
| | us | 5 | 9 | 4 | 8 | 7 | 5 | 7 | 9/7/99 | Sommer, et al. | 514 | 12 | | |
| | us | 6 | 1 | 0 | 7 | 3 | 0 | 6 | 8/22/00 | Carpino, et al. | 514 | 303 | | |
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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | | | | | | | | | |
| | 129(5) Hartm | Bercu, et al., "Sex Differences in Growth Hormone (GH) Secretion by Rats Administered GH-Releasing Hexapeptide", Endocrinology 129(5), pp. 2592-2598 (1991) Hartman, et al., "Temporal structure of in vivo growth hormone secretory events in human", The American Physiological Society, pp. E101-E110 (1991) | | | | | | | | | | | | | |
| | Specif | Huhn, et al., "Twenty-Four-Hour Growth Hormone (GH)-Releasing Peptide (GHRP) Infusion Enhances Pulsatile GH Secretion and Specifically Attenuates the Response to a Subsequent GHRP Bolus", <u>Journal of Clinical Endocrinology</u> 76(5), pp. 1202-1207 (1993) Gevers, et al., "Growth, Growth Hormone (GH)-Binding Protein, and GH Receptors Are Differentially Regulated by Peak and Trough Components of the GH Secretory Pattern in the Rat", <u>Endocrinology</u> , pp. 1013-1018 (1996) | | | | | | | | | | | | 993) / | |
| | Clark, | Clark, et al., "Paradoxical Growth-Promoting Effe Patterned Infusions of Somatostatin", Endocrinology, pp. 2675-2682 (1988) Clark, et al., "Intravenous growth hormone: growth responses to patterned infusions in hypophysectomized rats", J. Endocr. 104, pp. 53-61 (1985) | | | | | | | | | | | , pp. | | |
| | Robin | Robinson, "Chronopharmacology of growth hormone and related peptides", Advanced Drug Delivery Reviews 6, pp. 57-82 (1991) | | | | | | | | | | | | | |
| | Smith | Smith, et al., "Peptidomimetic Regulation of Growth Hormone Secretion", Endocrine Reviews 18(5), pp. 621-645 (1997) | | | | | | | | | | | | | |
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